MAR 1 9 2002

510(K) SUMMARY
(Based on 21 CFR Part 807.92)

Submitted By:
Wilson-Cook Medical Inc.
4900 Bethania Station Road
& 5951 Grassy Creek Boulevard
Winston-Salem, NC 27105

Device Description:
The Wilson-Cook Modified Multiple Band Ligator is used to ligate internal hemorrhoids. This device is supplied non-sterile and intended for single use only.

Trade Name: Wilson-Cook Multiple Band Ligator

Common/Usual Name: Multiple Band Ligator

Classification Name/Code: Ligator, Hemorrhoidal, GU, 78 FHN

Classification: FDA has classified similar devices as Class II, as per 21 CFR § 876.4400. This device falls within the purview of the Gastroenterology and Urology Device Panel.

Performance Standards: To the best of our knowledge, performance standards for this device do not exist.

Intended Use: Used to ligate internal hemorrhoids.

Predicate Device:

PREDICATE DEVICE	MANUFACTURER	DOCUMENT CONTROL NUMBER
Wilson-Cook Multiple Band Ligator	Wilson-Cook Medical	K944220/A

Substantial Equivalence:
The Wilson-Cook Modified Multiple Band Ligator is substantially equivalent to the referenced predicate device with respect to design, materials of construction and intended use.

DEVICE CHARACTERISTIC	Wilson-Cook Modified Multiple Band Ligator [Subject of Special 510(k)]	Wilson-Cook Multiple Band Ligator (K944220/A)
Intended Use	Used to ligate internal hemorrhoids.	Used to ligate esophageal varices at or above the gastroesophageal junction and to ligate internal hemorrhoids.
Sterility	Non-sterile, Disposable	Non-sterile, Disposable

The modification of the predicate Wilson-Cook Multiple Band Ligator (K944220/A) consists of a change to the handle in order to accommodate single-hand operation through an anoscope. In addition, the modified device comes preloaded with the barrel attached to the tip of the handle. The predicate device is designed for attachment to the end of an endoscope, while the

510(K) SUMMARY (continued)

modified Multiple Band Ligator is used in conjunction with an anoscope.

The barrel and bands of the modified device are identical to those of the predicate Wilson-Cook Multiple Band Ligator in the materials of construction and the specifications of each. The trigger cord is comprised of the same materials, however the Vectran string used is slightly shorter in length for the modified device, as it does no longer need to fit the length of an endoscope. Because the modified device comes preloaded, a friction fit adapter, loading catheter and irrigation adapter are not needed.

It is also important to note that both the predicate and the modified device share the same intended use, share similar methods of operation, and are comprised of the same raw materials.

Biocompatibility:

Reasonable assurance of biocompatibility for the patient-contacting materials has been established through a history of use in similar patient-contacting medical devices and, as applicable, biocompatibility test results.

Design Control/Risk Analysis/Design Verification:

Design Control, Risk Analysis, Design Verification activities for the subject of this special 510(k) have been conducted in accordance with all applicable internal procedures. The design control process employed is inclusive of the elements as stipulated by 21 CFR Part 820.30, as applicable to the project. The risk analysis performed identified the risks relative to the performance requirements, as specified by our internal procedure for Risk Analysis. The failure mode, effect of failure, severity, potential cause, rate of occurrence, design control element/production controls to eliminate, the potential to detect and our recommended actions were also documented. During Design Verification, dimensional and functional testing to ensure the performance and design integrity of this product line were conducted. All results obtained during our Design Verification met our predetermined acceptance criteria for this product line.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2002

Ms. Margaret J. Posner
Regulatory Affairs Specialist
Wilson-Cook Medical
GI Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K020526
Trade/Device Name: Wilson-Cook Multiple Band Ligator (Device Modification)
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: 78 FHN
Dated: February 13, 2002
Received: February 19, 2002

Dear Ms. Posner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020526

Device Name: Wilson-Cook Multiple Band Ligator

Indications for Use:

Used to ligate internal hemorrhoids.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Lagerm

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020526